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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
KIM, YOUNG J

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/14/2002 24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/233,218	CAJACOB ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/15/02.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 10-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 22 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Written Description Guideline* .

DETAILED ACTION

Applicants are advised that the instant application, after careful reconsideration, has been reopened for prosecution.

Information Disclosure Statement

Applicants are advised that the information disclosure statement filed on May 15, 2002 (Paper No. 22) will be considered since the finality status of the instant application is withdrawn.

Claim Rejections - 35 USC § 101 / 112 1st Enablement

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 11-21 under 35 U.S.C. 101 for lacking patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility, in the Office Action mailed on December 17, 2001 is maintained for the reasons of record.

Applicants' arguments received on May 15, 2002 have been fully considered but they are not found persuasive.

Applicants state claims 11-21 were "erroneously" rejected under 35 U.S.C. 101 because the analysis misstated, "the nature of the asserted uses, ignor[ed] the disclosed utilities, and misappli[ed] the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*," reciting that an invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." (pp. 4).

However, the instant situation is analogous to that which was addressed in the cited *Brenner v. Manson*, 148 USPQ 689 (1966), wherein the court expressed the opinion that all

chemicals are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which requires that an invention must have either an **immediately apparent** or fully disclosed "real world" utility (emphasis added). The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form there is insufficient justification for permitting an appellant to engross what may prove to be a broad field...a patent is not a hunting license...[i]t is not a reward for the search, but compensation for its successful conclusion.

Applicants have given a list of utilities that are applicable to any nucleic acids in general by the virtue of their inherent property, that is, the ability to hybridize to their complement. The list recites, identifying the presence or absence of a polymorphism, and use as a hybridization probe for expression profiling (pp. 52, line 3 through page 53, line 5; pp. 83, line 9 through page 91, line 3; pp. 71, lines 4-13). Applicants also state there would be no need to rely solely on the use of the disclosed SEQ ID Numbers to encode Glu TR (Glutamy tRNA reductase), or fragments thereof, to prove the utility of the claimed invention.

However, the utilities addressed by the Applicants (except Glu TR), are considered to be non-substantial (or lack real world application or immediate benefit) as set forth in the previous Office Action because the claimed nucleic acids, by their presence or absence, or as probes, do not relay a real-world applicability to a skilled artisan. The nucleic acids as disclosed, do not provide to one of ordinary skill in the art, what the presence or the absence of the claimed

nucleic acids would be useful for. For a nucleic acid to have a **substantial or real-world** utility, its presence or absence must relay to the artisan a real-world applicable information, such as detection/predisposition of certain conditions (i.e., cancer markers) (emphasis added). A blanketed statement indicating that the nucleic acids have a substantial utility because they can detect polymorphisms (although they are not polymorphisms themselves) would not give an **immediately apparent,** or substantial utility as court has expressed because such apparent utility would not be found without conducting further research on whether each of the nucleic acids would be useful in detecting any (if at all) polymorphisms.

Applicants' argument drawn to the claimed nucleic acid being useful as probes are not found persuasive as set forth in the previous Office Action because any nucleic acids, by their inherent property, would hybridize to their complement. However, the hybridization of such nucleic acid must relay to an ordinarily skilled artisan some real-world applicability. A nucleic acid could certainly be used as for example, a probe for detecting a condition (i.e., marker), a primer for amplifying a region which would serve as an indication of something, determining the location of a corresponding DNA sequence on a physical or genetic map and thus determining the function of a gene, etc. However, the claimed nucleic acids lack a substantial utility because the specification of the instant application fails to provide any guidance in correlating the presence/absence of the claimed nucleic acids to some known disease, condition, or presence of harmful agents (i.e., bacteria), etc. Applicants simply rely on the fact that the probes have been patentable in the art and since the claimed nucleic acids **can be** used as probes, they must be patentable. Such argument is not found persuasive because nucleic acid probes are not patented solely on their ability to hybridize to their complement. It is the information (an immediately

useful benefit) which is derived from the hybridization. Applicants have failed to give any example or guidance in what the presence/absence or the overexpression/underexpression of the claimed nucleic acids would relay to an ordinarily skilled artisan, other than reciting a general list of what nucleic acids **could** be useful for. The artisan using the nucleic acids of the instant application would not know why the artisan should use the claimed nucleic acids over any other nucleic acids that are derived from soybean or maize. Without further research, the artisan would not have any reason, such as an immediately apparent benefit, to use the claimed nucleic acids over other nucleic acids that are isolated from soybean or maize.

Applicants attempt to attribute utility to the claimed nucleic acids through the use of a microscope analogy. A microscope, by virtue of the invention, has a real world application in magnifying microscopic objects (that are known to exist) to which the human eyes are not capable of seeing. The real world application of a nucleic acid, however, does not lie in its inherent property of hybridizing to its complement. The nucleic acid, by its hybridization or amplification, must infer useful information. It is that useful information (immediately useful benefit) which would give substantial utility to a nucleic acid. The instant application has failed to disclose such information to the artisan in question. Applicants also sate that the use of claimed nucleic acid molecule to detect the presence or absence of polymorphism is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas. This argument is not found persuasive because an artisan will be led to use a gas chromatograph for identifying, via separation, the contents of the elements in the gas, which is an immediate benefit to the artisan in question. However, Applicants have not given any immediately apparent benefit (substantial utility) for the artisan to use the claimed nucleic acids for detection of

polymorphisms over any other nucleic acids isolated from soybean or maize. An immediately apparent benefit that would lead the artisan to use a nucleic acid to detect the presence/absence polymorphism would be for, for example, a cancer diagnostic (mutations in BRCA 1 and BRCA 2 which increase the likelihood of breast and ovarian cancer). Such disclosure would allow the artisan to realize the immediate benefit of using such nucleic acids for detection of polymorphism over any other nucleic acids. Applicants have failed to give any immediate benefit in why the artisan would benefit from using the claimed nucleic acid for the detection of polymorphisms.

Applicants' also attempt to attribute utility to the claimed nucleic acids through the use of a golf club analogy. In accordance with the Applicants' example, a golf club is useful and has utility in hitting a "golf ball," not any object. Its utility lies in hitting a golf ball. Similarly, the utility of a nucleic acid lies in what information it infers. Such information could be, "what does the presence/absence of the nucleic acid indicate," what region does the nucleic acid amplify that gives significance," what is the function of its encoded protein," etc. The instant application has failed to give such guidance to the artisan in question.

With regards to the Applicants' argument drawn to the nucleic acid having a specific utility, any piece of nucleic acid is considered to be "specific" to its complement. However, the claimed nucleic acids lack substantial utility as discussed above.

With regard to the Applicants' argument stating that the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the Unites States is not found persuasive because the patentability of a subject matter is not hinged on the degree of public interest but rather on the statues under 35 U.S.C.

With regard to the Applicants' argument stating that functionality attributed from similarity, it appears that Applicants have not provided any convincing evidence other than references that indicate the general nature in comparative sequencing in investigating the structure and function of a molecule. Although such method is practiced among artisans, Iyer et al., (Genome Biology, 2001, vol. 2, no, 12) discloses the unpredictability in relying on computational prediction (i.e., homology assessment) in assigning protein's function from sequence homologies (Abstract). Iyer et al. discloses evidences for rejecting the, "homologous relationships and functional predictions inferred for the proteins in question by using computational method." (pp. 8), thus substantiating the unpredictability in the Applicants' asserted protein function, rendering the claims lack substantial utility for the claimed nucleic acids.

For the foregoing reasons, the claimed nucleic acid lack patentable utility as required under 35 U.S.C. 101.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 11-21 under 35 U.S.C. 112, 1st paragraph (because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility) for the reasons set forth above, one skilled in the art would not know how to use the claimed invention, in the Office Action mailed on December 17, 2001 is maintained for the reasons of record.

Applicants' arguments received on May 15, 2002 have been fully considered but they are not found persuasive for the reasons indicated above.

The rejection of claims 1, 2, and 10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, in the Office Action mailed on December 17, 2001, is maintained for the reasons of record.

Applicants' arguments received on May 15, 2002 have been fully considered but they are not found persuasive for the reasons set forth below.

Applicants are advised that the enablement rejection was based on the determination that the claimed nucleic acids do not have the asserted Glu TR activity. Applicants state that performing routine and well known steps, such as sequence alignment protocols, molecular weight determination, and antibody hybridization assays, cannot create undue experimentation even if it is laborious. However, if the claimed nucleic acids do not encode a Glu TR, no matter how routine the experimentation might be, the nucleic acids cannot be used as the claims intended purpose.

Applicants state that the specification provides evidence based on sequence identity (Table A) that the disclosed genes encode polypeptide having Glu TR activity. This is considered to be an assertion based on the sequence homology and not an evidence demonstrative of the claimed nucleic acids actually encoding polypeptides having the asserted Glu TR activity. The specification discloses that comparison of the deduced amino acid

sequence (encoded by the claimed nucleic acids) exhibit about 60% overall similarity with stretches of amino acid identity. Applicants also state that in particular, barely, *Arabidposis*, and cucumber exhibit over 70% identity at the deduced amino acid level (pp. 14), leading to the conclusion that sequence homology is indeed an adequate and predictable indicator Glu TR functionality. This point is not found persuasive as already set forth because Iyer et al., (Genome Biology, 2001, vol. 2, no, 12) discloses the unpredictability in relying on computational prediction (i.e., homology assessment) in assigning protein's function from sequence homologies (Abstract). Iyer et al. discloses evidences for rejecting the, "homologous relationships and functional predictions inferred for the proteins in question by using computational method." (pp. 8). Applicants have failed to give any evidence via example that the claimed nucleic acids indeed had this functionality. Absent evidence to the contrary, it is determined that it would require undue experimentation from a skilled artisan to use the claimed nucleic acids as Glu TR because the nucleic acid would not have this function.

Claims 1, 2, 10, and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are advised that the instant rejection includes claim 11 which was erroneously excluded in the previous Office Action. As to claims 1, 2, and 10, the rejection is being maintained as set forth in the Office Action mailed on December 17, 2001.

Applicants' argument received on May 15, 2002 have been fully considered but they are not found persuasive.

Applicants state that if the written description rejection made by the Office was proper, then every claim containing the term "comprising" would be invalid for failing to describe every nuance of the claimed invention (pp. 16, bottom). To the contrary, the Office does issue patents on claims which contain "comprising" language (i.e., methods, products which meet the requirement). However the presently claimed nucleic acids fail to meet the requirement because the specification fails to disclose a full open reading frame for each of the claimed SEQ ID Numbers. Therefore, a nucleic acid "comprising" such SEQ ID Number would read on an undescribed region of a full-length cDNA as well as a gene sequence.

Applicants argue that the term "comprising" is used with the intention of covering molecules that include the recited sequences with additional sequences, or that hybridize under specific conditions to the recited sequences (pp. 17, bottom). Applicants argue that these "additional sequences" were described in the specification since vectors comprising the claimed nucleic acids (specification pp. 36, 40, 109, and 118), extra nucleotides or detectable labels added to the claimed nucleic acids (specification pp. 58, 75, 76, 77, 161, and 162). Although these embodiments could very well be envisioned by a skilled artisan, the fact remains that the claims also read on a full-length cDNA or a gene sequence. It would not be possible for the skilled artisan to envision that Applicants had possession of such molecules nor would it be within the purview of a skilled artisan to fabricate a full-length cDNA or gene sequence which "comprise" the claimed nucleic acids based on the specification or the prior art.

Applicants are advised that the Written description rejection is based on the policy of the technology center attached to the present Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Baysdorfer (Accession Number W21756 on GenBank, May 1996).

Claim 1 is drawn to a nucleic acid molecule that encodes a maize or soybean tetrpyrrole pathway enzyme or **fragment thereof**, wherein said enzyme is a glutamyl-tRNA reductase.

Baysdorfer discloses a cDNA sequence of Zea mays glutamyl-tRNA reductase that has a overall homology of 76.8% to SEQ ID Number 586, thus encoding a fragment of the claimed enzyme.

Therefore, Baysdorfer anticipates the invention as claimed.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose teleph ne number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the

Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

8/8/02

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
8/12/02